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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,257	12/03/2001	Merrit N. Jacobs	961_009	1338

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,257	JACOBS ET AL.	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,12,18,23,29 and 35-47* is/are rejected.

7)☒ Claim(s) *2-6, 8-11, 13-17, 19-22, 24-28, 30-34, 48-49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12-30-01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 1-49 are objected to because of the following informalities:

Claims 1-11, and 48 are essentially duplicate claims to claims 12-22 and 49, respectively. The only difference in independents claim 1 and 12 is in the dispensing step. Claim 12 specifies that the liquid is dispensed into a reaction vessel while claim 1 does not specify any target area for dispensing. The specification discloses that only location for dispensing the liquid is into reaction vessels. Therefore, the interpretation or scope the claims in view of the specification are directed to the same identical method.

Claims 23-35 are essentially duplicate claims to claims 36-47, respectively. The only difference in independents claim 23 and 36 is in the preamble. Applicant has elected to refer to the invention of claim 36 as a "clinical analyzer". However the elements of the "clinical analyzer" are the same elements of the device of claim 23. No structural differences exist between the devices. Applicant has merely chosen to refer to the invention by two different names.

The recitation of the device being "a clinical analyzer" has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951)

Claim 1 and 12 recite the step of modifying said variable fluid rate flow profile using said pump motor.

The profile of the variable fluid flow rate is given in the form of some graphical presentation. The profile is generated from data directed to the changes in velocity with respect to time. Therefore, it is inherent that if one chooses to change the speed of a pump during a aspiration/dispensing process, that upon graphing the speed of the pump versus time would reveal change that would not be the same as the graph of the process without the change.

It appears as applicant is modifying or changing the speed during aspiration/dispensing which results in a change in a profile that can be seen in a graphical presentation presented in form of manually drawn graph, graph generated from an interfaced electrical printer, or computer monitor.

The appropriate claim would be to recite changing/modifying the speed variable fluid flow rate via said pump motor during at least one of said aspirating and dispensing steps so as to effect the relative velocity of dispensed fluid, wherein said change/modification results in a change/modification of the fluid flow rate profile.

Appropriate correction is required.

Claim Interpretations

2. It has been determined that a change in pumping speed during aspiration or dispensing inherently results in a change in the profile of the process. As such any process that teaches changing the pump speed also inherently teaches changing the profile of a aspirating and dispensing process.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 12, 23, 36-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 recite the limitation of "said pump including a pump". This is improper however the examiner assumes applicant's intent is to claim a pump motor as recited in the "modifying" step.

Claims 1 and 12 recite "modifying said variable fluid rate flow profile using said pump motor during **at least one of said aspirating and dispensing** steps so as to effect the relative velocity of dispensed fluid." It is unclear how a change in the in flow rate during aspiration would affect the flow rate of the liquid being dispensed (or vice versa). There is no indication that operations (speed of dispensing and aspirating) directly or indirectly affect one another.

As to claims 23 and 36, it is unclear what physical structure applicant considers as the "means for modifying the fluid rate profile". As explained above and evidenced by applicants drawings the fluid rate profile is a graphical representation of what changes (if any) occur in relationship to time during a dispensing/aspiration process. The pump of the device changes the speed of the fluid, which results in a change in the profile. The examiner fails to locate where applicant provides support to claim such a

means for modifying the profile that is different from the pump. The pump and the means for modifying are the same elements.

Claims 36-47 refer to the invention as "a clinical analyzer". It is unclear how the metering system alone may be considered an analyzer. There is no structure claimed that possesses the ability to provide for any type of analysis. The elements of the claims are directed to a metering or pumping system.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 7, 12, 18, 23, 29, 35, 36, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Liseo et al. US 2001/0039053.

Liseo et al. disclose an apparatus for transporting various volumes of fluids having different viscosities into and out of a slide assembly includes a database storing data for fluids, including duration of slide assembly filling, duration of slide assembly purging and duration of slide assembly rinsing, and a controller responsive to an input which corresponds to a fluid sample selected from body fluids and having an aspiration mode, wherein the controller monitors filling of the slide assembly, a purging mode, wherein the controller monitors purging of the slide assembly and a rinsing mode,

wherein the controller monitors rinsing of the slide assembly over respective durations determined by the database.

The device comprises aspiration probe 24 (dispense nozzle), saline and bleach contained in containers 34, 36, respectively (fluid supply), which are preferably mounted on a tray 42 to the interior of the probe, pump 28, a reversible peristaltic pump driven by a stepper motor 50, and a central processing unit 46 programmed to carry out a plurality of microinstructions defining the individual operations and their durations in response to a fluid sample selection made by a user on a menu 44. Preferably, the CPU 46 is an off-the-shelve microprocessor controlling a direction of rotation and speeds of the pump 28 in response to signals generated by a variety of pressure and optical sensors 54, 56. Also, the microprocessor controls valve arrangements 52 upon querying a database 48.

During aspiration of fluid sample into the optical slide 26 assembly through the aspiration probe 24, the pump's piston is displaceable in a direction of arrow "A" creating negative pressure downstream from the test tube 22 to draw a fluid sample into the slide assembly 26. In order to implement this mode, the valve 64 is energized to enable its normally closed port to open. Upon a predetermined period of time sufficient for displacing the nominal volume of tested fluid, as explained above, the valve 64 is de-energized allowing a user to conduct examination of the fluid sample.

To purge the fluid sample out of the slide assembly 26 back to the tube 22, the valve 64 is once again energized providing a passage for flushing fluid, which displaces the fluid sample following reversal of the pumping direction of pump 28 (change in flow rate) into the waste basin 40.

Allowable Subject Matter

7. Claims 2-6, 8-11, 13-17, 19-22, 24-28, 30-34, 48, and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 37-41, 43-49 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach nor fairly suggest a method step of modifying profile step includes the step of offsetting a reference position of said pump motor in order to shift at least a portion of said fluid flow rate profile, said profile modifying step includes the step of applying a variation in motor speed according to a profile having a shape which is inverted relative to said fluid flow rate profile, a variable speed pump produces a sinusoidal fluid flow rate profile in which the beginning and end of said dispensing steps produce a fluid flow rate of zero from the dispense nozzle, said modifying step including the step of increasing the speed of the pump motor along portions of said profile in order to increase the fluid flow rate.

The prior art also fails to teach a modifying profile means that includes means for offsetting a reference position of said pump motor in order to shift at least a portion of said fluid flow rate profile.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Merten, C. William et al.; Tisone, Thomas C. et al.; Liseo, John et al. ; Shvets, Igor et al.; Tisone, Thomas C.; Pelc, Richard E. et al.; LaBudde, Edward V. et al.; Rose, Don et al.; Papen, Roeland F.; Pfost, Dale R. et al.; Schmider, Paul et al.; Parker, and Bernard et al. disclose fluid pumping and transfer systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

brg

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